

DMB

Display Date	10-27-99
Publication Date	10-28-99
Certifier	M. Beal

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-2549]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Cosmetic Product Voluntary Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by *(insert date 30 days after date of publication in the Federal Register)*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Cosmetic Product Voluntary Reporting Program—21 CFR 720.4, 720.6, and 720.8(b) (OMB Control Number 0910–0030—Extension)

Under the Federal Food, Drug, and Cosmetic Act (the act), cosmetic products that are adulterated under section 601 of the act (21 U.S.C. 361) or misbranded under section 602 of the act (21 U.S.C. 362) cannot legally be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, FDA requests under part 720 (21 CFR part 720), but does not require, that firms that manufacture, pack, or distribute cosmetics file with the agency an ingredient statement for each of their products (§ 720.4). Ingredient statements for new submissions (§ 720.1) are reported on Form FDA 25 12 entitled “Cosmetic Product Ingredient Statement,” and Form FDA 2512a, a continuation form. Changes in product formulation (§ 720.6) are also reported on Forms FDA 25 12 and FDA 25 12a. When a firm discontinues the commercial distribution of a cosmetic, FDA requests that the firm file Form FDA 2514 entitled “Discontinuance of Commercial Distribution of Cosmetic Product Formulation” (§ 720.6). If any of the information submitted on or with these forms is confidential, the firm may submit a request for confidentiality under § 720.8.

FDA uses the information received on these forms as input for a computer-based information storage and retrieval system. These voluntary formula filings provide FDA with the best information available about cosmetic product formulations, ingredients and their frequency of use, businesses engaged in the manufacture and distribution of cosmetics, and approximate rates of product discontinuance and formula modifications. FDA’s data base also lists cosmetic products containing ingredients suspected to be carcinogenic or otherwise harmful to the general public health. The information provided under the Cosmetic Product Voluntary Reporting Program assists FDA scientists in evaluating reports of alleged injuries and adverse reactions to the use of cosmetics. The information also is utilized in defining and planning analytical and toxicological studies pertaining to cosmetics.

FDA shares nonconfidential information from its files on cosmetics with consumers, medical professionals, and industry. For example, by submitting a Freedom of Information Act request, consumers can obtain information about which products do or do not contain a specified ingredient and about the levels at which certain ingredients are typically used. Dermatologists use FDA files to cross-reference allergens found in patch-test kits with cosmetic ingredients. The Cosmetic, Toiletry, and Fragrance Association, which is conducting a review of ingredients used in cosmetics, has relied on data provided by FDA in selecting ingredients to be reviewed based on frequency of use.

The Cosmetic Product Voluntary Reporting Program was suspended during fiscal year (FY) 1998 because of a lack of funding and was reinstated at the beginning of FY 1999. Participation returned to the previous level. Thus, FDA estimates that the burden of this collection of information will remain the same as the estimate presently on file with OMB.

In the **Federal Register** of August 9, 1999 (64 FR 431 88), the agency requested comments on the proposed collections of information. One comment was received in support of the continuation of the program.

TABLE 1 .-ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
720.4 (New submissions)	FDA 2512/ FDA 2512a	550	4.2	2,310	0.5	1,155
720.6 (Amendments)	FDA 2512/ FDA 2512a	550	1.4	770	0.33	254
720.6 (Notices of discontinuance)	FDA 2514	550	4.5	2,500	0.1	250
720.8 (Requests for confidentiality)		2	1.0	2	1.5	3
Total						1,662

There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on the number and frequency of submissions received in the past and on discussions between FDA staff and respondents during routine communications. The actual time

required for each submission will vary in relation to the size of the company and the breadth of its marketing activities.

Dated: October 21, 1999



William K. Hubbard
Senior Associate Commissioner
for Policy, Planning and Legislation

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01 -F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

